Remarks

Claims 1-56 were initially pending in the subject application. In response to a restriction requirement, claims 1-16, 30, and 51-52 were elected for examination on August 16, 2000. By way of the amendment of this date, claims 57-58 have been added. Therefore, claims 1-16, 30, 51-52 , and 57-58 are now before the Examiner for consideration. The subject invention provides unique and advantageous *Chlamydia trachomatis* polynucleotides, vectors, transformed host cells, DNA chips, and kits containing the aforementioned polynucleotides. Certain of the claims have been amended for the purpose of expediting the patent application process in a manner consistent with the Patent and Trademark Office Patent Business Goals (PBG), 65 Fed. Reg. 54603 (September 8, 2000), advancing prosecution, and facilitating the business interests of Applicants. Support for these new claims and the amendments to the pending claims can be found throughout the subject specification, including, for example, the originally presented claims or at pages 8-9. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The Office Action of April 17, 2001 has objected to the title of the application, asserting that the title is not descriptive of the subject matter to which the claims are directed. Applicants have amended the title and believe this issue to be moot.

Claims 1-16, 30, and 51-52 have been rejected under 35 U.S.C. §101 as lacking patentable utility due to its not being supported by either a specific and/or substantial utility or a well-established utility. The Office Action alleges that the specification fails to connect the claimed invention to any particular or specific utility and that no substantial utility has been established for the claimed subject matter. Applicants respectfully traverse.

Applicants submit that the claimed subject matter has patentable utility (*i.e.*, "specific", "substantial", "credible", and "well-established" utility) and meets the definitions set forth in the Office Action of April 17, 2001 at pages 2-3. Particularly, the claimed nucleic acids are useful as hybridization probes for the detection of *C. trachomatis*. As evidence of such usefulness, it is respectfully submitted that the art generally recognizes and practices the detection of *Chlamydia trachomatis* in biological samples by utilizing nucleic acid detection methodologies. These detection methodologies include PCR and/or hybridization assays (see attached ViroMed Laboratories and GEN-PROBE publications and references cited therein). As is evident from these publications, one

skilled in the art would recognize a "well-established" utility for the disclosed polynucleotide sequences as reagents for the detection of *Chlamydia trachomatis* infections in humans in PCR or hybridization assays and such a use would have been readily apparent to one skilled in the art alone, or in view of the instant disclosure, and/or in view of the knowledge of the skilled artisan.

Furthermore, the disclosure of the instant specification, alone or in combination with the publications provided in this response, support, "specific", "substantial", and "credible" utilities for the instant subject matter. As the Examiner will recognize, the claimed polynucleotide sequences are useful as hybridization probes or PCR probes for the detection of *C. trachomatis* in biological samples by virtue of the sequences having been obtained from this organism. Furthermore, a "substantial" utility can be assigned to the claimed polynucleotides because nucleic acid assay systems are commercially available or are provided by "real-world" vendors that utilize *C. trachomatis* nucleic acid probes within their assay systems. Thus, the claimed polynucleotide sequences would be useful in such assay systems. Finally, the asserted utility of the invention in nucleic acid detection assays (either PCR-based systems: specification at page 49, lines 25-29; or hybridization assays: page 51, lines 3-31) is credible as assessed from the perspective of one of ordinary skill in the art. Thus, it is respectfully submitted that the claimed polynucleotide sequences possess a patentable utility and withdrawal of the rejection is respectfully requested.

Claims 1-16, 30, and 51-52 have been rejected under 35 U.S.C. § 112, first paragraph, because one skilled in the art would not know how to use the claimed subject matter because the claimed invention is not supported by a specific, substantial, and credible utility, or alternatively, a well-established utility. As indicated *supra*, it is respectfully submitted that the claimed polynucleotide sequences are useful in nucleic acid based assays for the detection of *C. trachomatis* in biological samples. As such, it is respectfully submitted that one skilled in the art would know how to use the claimed subject matter. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-16, 30, and 51-52 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the invention was filed, had possession of the claimed invention. Applicants respectfully traverse.

The subject invention is directed to novel and non-obvious open reading frames identified and isolated from *Chlamydia trachomatis*. It is respectfully submitted that one skilled in the art can readily envisage nucleic acid sequences containing the recited ORFs because these nucleic acids can be readily inserted into known replication vectors. Applicants also respectfully submit that one skilled in the art would be able to readily envisage nucleic acid sequences having 80% or 99.9% homology to the claimed ORFs. Accordingly, withdrawal of the rejection is respectfully requested.

The subject invention also provides polynucleotides that hybridize with the open reading frames of the invention, provided that the hybridizing polynucleotides have at least 80% or 99.9% homology to the complementary polynucleotide sequences of the claimed ORFs. Given that the full length open reading frames of the invention are provided in the disclosure, Applicants respectfully submit that one skilled in the art would be able to envision the sequences having the required degree of homology to the complementary open reading frames. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1-7, 51, and 52 have been rejected under 35 U.S.C. §§ 102(a) or 102(b) as being anticipated by a variety of Genbank accession numbers. Applicants respectfully submit that the prior art applied in the Office Action does not anticipate the claimed sequences and fails to teach these same polynucleotide sequences. Furthermore, it is respectfully submitted that the prior art polynucleotide sequences fail to demonstrate the requisite degree of homology necessary to sustain an anticipation rejection for hybridizing polynucleotide sequences. Reconsideration and withdrawal of the rejections is respectfully requested.

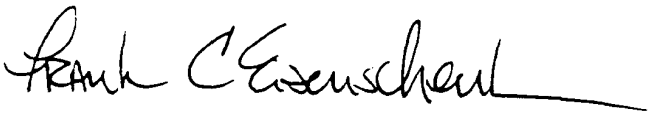
Claims 1-7, 9-11, 13, 15, 51, and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Genbank sequences. The Office Action states that it would have been obvious to one of skill in the art to link the Genbank sequences to regulatory elements, prepare transformed host cells containing the sequences in operatively linked vectors, and make complements of the sequences. It is well settled law that all the claim limitations must be taught or suggested by the prior art to establish *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants respectfully submit that the Genbank sequences do not teach the claimed polynucleotide sequences nor do the Genbank sequences teach all the limitations found in the claims. Withdrawal of this obviousness rejection is respectfully requested.

Claim 30 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Genbank sequences in view of Southern *et al.* (U.S. Patent No. 5,436,327). The Office Action states that the Genbank sequences describe nucleic acid sequences within the scope of the instant claims and Southern *et al.* teach the preparation and use of DNA chips. Applicants respectfully submit that the Genbank sequences do not constitute prior art applicable to the claims, fail to teach each and every limitation of the claims, and, therefore, the rejection fails to raise a *prima facie* case of obviousness for claim 30. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

In view of the foregoing remarks and the amendments to the claims, Applicants believe that the pending claims are now in condition for allowance, and such action is respectfully requested. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments:
- Marked-Up Version of Amended Title
- Marked-Up Version of Amended Claims
- "C. Trachomatis & N. Gonorrhoeae PCR", ViroMed Laboratories, October 2000
- "Chlamydia Trachomatis and Neisseria Gonorrhoeae", Gen-Probe Inc., 103906 Rev. K/April 17, 2001

Marked-up Title

~~CHLAMYDIA TRACHOMATIS GENOMIC SEQUENCE AND POLYPEPTIDES, FRAGMENTS THEREOF AND USES THEREOF, IN PARTICULAR FOR THE DIAGNOSIS, PREVENTION AND TREATMENT OF INFECTION~~

CHLAMYDIA TRACHOMATIS NUCLEIC ACIDS AND USES THEREOF

Marked-up Claims

Claim 1 (Amended):

An isolated polynucleotide ~~having a nucleotide~~ sequence ~~of a~~ obtained from *Chlamydia trachomatis* ~~genome.~~ comprising the polynucleotide sequence of SEQ ID NO. 1083, SEQ ID NO. 1089, SEQ ID NO. 1091, SEQ ID NO. 1095, SEQ ID NO. 1096, SEQ ID NO. 1105, SEQ ID NO. 1117, SEQ ID NO. 1140, SEQ ID NO. 1159, or SEQ ID NO. 1167; or

an isolated polynucleotide sequence having at least 80% homology to SEQ ID NO. 1083, SEQ ID NO. 1091, SEQ ID NO. 1095, SEQ ID NO. 1096, SEQ ID NO. 1105, SEQ ID NO. 1117, SEQ ID NO. 1140, SEQ ID NO. 1159, or SEQ ID NO. 1167; or

an isolated polynucleotide sequence having at least 99.9% homology to SEQ ID NO. 1089, SEQ ID NO. 1083, SEQ ID NO. 1091, SEQ ID NO. 1095, SEQ ID NO. 1096, SEQ ID NO. 1105, SEQ ID NO. 1117, SEQ ID NO. 1140, SEQ ID NO. 1159, or SEQ ID NO. 1167.

~~(a) the nucleotide sequence of SEQ ID No. 1;~~

~~(b) the nucleotide sequence contained within the *Chlamydia trachomatis* genomic DNA in ECACC Deposit No. 98112618;~~

~~(c) the nucleotide sequence contained in a clone insert in ECACC Deposit No. 98112617;~~

~~(d) a nucleotide sequence exhibiting at least 99.9% identity with the sequence of SEQ ID No. 1; or~~

~~(e) a nucleotide sequence exhibiting at least 80% homology to SEQ ID No. 1.~~

Claim 2 (Amended):

An isolated polynucleotide ~~which hybridizes to SEQ ID No. 1 or to the *Chlamydia trachomatis* genomic DNA contained in ECACC Deposit No. 98112618 or to a clone insert in ECACC Deposit No. 98112617 under conditions of high stringency.~~ that hybridizes to a *Chlamydia trachomatis* polynucleotide sequence comprising the sequence of SEQ ID NO. 1083, SEQ ID NO. 1089, SEQ ID NO. 1091, SEQ ID NO. 1095, SEQ ID NO. 1096, SEQ ID NO. 1105, SEQ ID NO. 1117, SEQ ID NO. 1140, SEQ ID NO. 1159, or SEQ ID NO. 1167, under conditions of high stringency, wherein said hybridizing polynucleotide sequence has at least 80% homology to the

complementary sequence of SEQ ID NO. 1083, SEQ ID NO. 1091, SEQ ID NO. 1095, SEQ ID NO. 1096, SEQ ID NO. 1105, SEQ ID NO. 1117, SEQ ID NO. 1140, SEQ ID NO. 1159, or SEQ ID NO. 1167, or at least 99.9% homology to the complementary sequence of SEQ ID NO. 1089.

Claim 3 (Amended):

An isolated polynucleotide ~~which hybridizes to SEQ ID No. 1 or to the *Chlamydia trachomatis* genomic DNA contained in ECACC Deposit No. 98112618 under conditions of intermediate stringency.~~ that hybridizes to a *Chlamydia trachomatis* polynucleotide sequence comprising the sequence of SEQ ID NO. 1083, SEQ ID NO. 1089, SEQ ID NO. 1091, SEQ ID NO. 1095, SEQ ID NO. 1096, SEQ ID NO. 1105, SEQ ID NO. 1117, SEQ ID NO. 1140, SEQ ID NO. 1159, or SEQ ID NO. 1167 under conditions of intermediate stringency, wherein said hybridizing polynucleotide sequence has at least 80% homology to the complementary sequence of SEQ ID NO. 1083, SEQ ID NO. 1091, SEQ ID NO. 1095, SEQ ID NO. 1096, SEQ ID NO. 1105, SEQ ID NO. 1117, SEQ ID NO. 1140, SEQ ID NO. 1159, or SEQ ID NO. 1167or at least 99.9% homology to the complementary sequence of SEQ ID NO. 1089.

Claim 8 (Amended):

A polynucleotide encoding a fusion protein, comprising one of ORF2 to ORF 1197 of Claim ~~4, 5 or 6~~ 1, 2 or 3 ligated in frame to a polynucleotide encoding a heterologous polypeptide.